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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/456,042	12/06/1999	ROBERT F. BONNER	15280-347100	5889

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[REDACTED] EXAMINER

GABEL, GAILENE

ART UNIT	PAPER NUMBER
1641	13

DATE MAILED: 08/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Offic Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/456,042	BONNER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 May 2002.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 16-46 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-15 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-46 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |                                                                                                |                                                                              |
|------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

## DETAILED ACTION

### *Amendment Entry*

1. Applicant's amendment and response filed 5/3/02 in Paper No. 12 is acknowledged and has been entered. Claims 1-13 and 15 have been amended. Currently, claims 1-46 are pending. Claims 1-15 are under examination.

### Rejections Maintained

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-15 are indefinite and incomplete for omitting essential structural and functional cooperative relationships between elements in the claims, such omission amounting to a gap between the necessary structural connections.

Claim 1 is indefinite and incomplete because in line 8, it appears that the activatable layer is locally contacted to a portion of a specimen; however, claim 1 fails to define that a laser "capture" microdissection from the specimen is necessarily effected as required by the preamble. Accordingly, claim 1 is incomplete for missing a correlation step that refers back to the requirement of the preamble.

Claim 3, line 3 is indefinite and inconsistent with claim 1 from which it depends in reciting, "visualizing the specimen" because it is unclear what antecedent "specimen" is being visualized, i.e. undissected specimen, contacted portion, captured portion (if any). Accordingly, it is also unclear how the recitation of "activating the selectively activatable layer overlying the visualized portion" in the instant claim relates to the "selectively activating" in claim 1 which causes volumetric expansion for contact. Specifically, claim 3 fails to distinctly define how the step of "selective activation" in the instant claim is distinct from the selective activation performed in claim 1. Please clarify.

In claim 5, it is unclear how the "surface" recited in line 3 relates or differs from the supporting substrate recited in claim 2.

Claim 5 recites inconsistent language in reciting, "exposed". Alternatively, claim 5 fails to distinctly define how the term "exposed" in the instant claim relates to the term "locally contact" recited in claim 1 from which it depends and in the instant claim.

Claim 5 is indefinite in reciting, "affinity specific bond with at least one part of the specimen" because it is unclear how "affinity specificity" is achieved between a "surface" and a "part of a specimen". Please clarify.

Claim 5 is vague and indefinite in reciting, "the portion of the specimen having the specific surface affinity defined by the surface on the activatable layer" because it is unclear how "specific surface affinity" is defined by the activated layer. Please clarify. Further, there is no antecedent basis for this recitation in the claim.

Claim 6 lacks clear antecedent support in reciting, "(repeating) the selectively activating of different portions of the selectively activatable layer".

Claim 6 lacks clear antecedent support in reciting, "different target elements within the specimen". It is specifically unclear how these targeted elements structurally or functionally relate to the "parts or specimen" or "portions of specimen", etc. previously recited. Alternatively, consistent claim language in making reference to the same element in a given set of claims is suggested, for consistency and clarity between claims.

Claim 7 is vague and indefinite in reciting, "moving the selectively activatable layer with respect to the specimen" because it is unclear what Applicant intends to encompass in the term "moving" as used in the claim.

Claim 8 is indefinite and incomplete because in lines 10-11, it appears that the activatable layer is locally contacted and bonded to a portion of a specimen; however, claim 10 fails to define that a laser "capture" microdissection from the specimen is necessarily effected as required by the preamble. Accordingly, claim 8 is incomplete for missing a correlation step that refers back to the requirement of the preamble.

Claim 9 is vague and indefinite in relation to claim 8 from which it depends in reciting, "contracting the volumetric expansion to separate ..." because it appears that the "allowing the volumetric expansion to cool" in claim 8 contracts the selectively activatable layer as set forth in lines 4-5. Accordingly, it is unclear what mechanism, distinct from the cooling step in claim 8, Applicant intends to encompass in such a recitation.

Claim 9, lines 4-6, is redundant and confusing. Perhaps, Applicant intends, "to separate and thus, microdissect, the targeted portion of the specimen from a remainder of the specimen". Please clarify.

Claim 10 is vague and indefinite in relation to claim 8 from which it depends in reciting, "contracting the volumetric expansion by cooling and maintaining attachment ..." because it appears that the "allowing the volumetric expansion to cool" in claim 8 contracts the selectively activatable layer as set forth in lines 4-5. As recited, the cooling step in the instant claim is separate from the cooling step in claim 8, i.e. the first one, not maintaining contact and the second one, maintaining contact, which does not appear to be Applicant's intent. Please clarify.

Claim 10 is ambiguous in reciting, 'to elastically tensioning the volumetric expansion ...'. Please correct.

Claim 10 is confusing in relation to claim 9 which also depends from claim 8 because in claim 10, the activatable layer is "withdrawn" to separate the (targeted) portion of the specimen from the remainder of the specimen; however, in claim 9, the volumetric expansion is only "cooled" to effect separation of the targeted portion. Please clarify.

Claim 10, lines 6-8, is redundant and confusing. Perhaps, Applicant intends, "to separate and thus, microdissect, the targeted portion of the specimen from a remainder of the specimen". Please clarify.

Claim 11 is confusing. Same analogous comments and problems in claims 9 and 10 apply to the "contracting step" in claim 11. Please clarify.

Claim 12 is ambiguous because it is unclear what Applicant intends to encompass in reciting, "providing ... strong long chain thermoplastic polymers with a large volume change".

Claim 15 has improper antecedent basis problem in reciting, "the a vapor bubble".

Claim 15 lacks antecedent support in reciting, "the first volume". Further, claim 15 fails to distinctly define how a vapor bubble structurally relates to the activatable layer and/or volumetric expansion.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Goldstein et al. (US 6,100,051) for reason of record.

Goldstein et al. disclose a process of laser capture microdissection from a specimen by selectively activating a selectively activatable layer (convex surface) causing a volumetric expansion of the layer. The activatable layer upon activation by a laser provides adhesive properties. The activatable layer is provided with a supporting substrate (distal end of a rod) and has a prepared adhesive transfer surface which forms a mechanical bond (maintains adhesion) to a portion of the specimen that is separated from the remainder of the specimen for visualization and analysis. The selectively activatable tissue is utilized to contact and capture targeted elements within a specimen, i.e. tissue sample (see Abstract and column 3). Goldstein et al. specifically disclose that the selectively activatable layer is made of heat (thermally) activatable materials which include strong long chain thermoplastic polymers and which undergo heat generated volumetric expansion such as ethylene vinyl acetate (EVA). EVA is preferred for its intrinsic absorption capability at 3 to about 10 micrometers (see columns 8-9 and column 11, lines 50-667). Solvents added thereto for solutions of hot-melt adhesive are matched for degree of effectiveness of the process and characteristics of the layer including evenness, smoothness, depth of the layer, and rate of cooling (drying) (see column 13).

**New Grounds of Rejection**

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 8-11, and 15-20 of U.S. Patent No. 6,420,132. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions use laser radiation to activate an activatable layer by heating the layer to cause an expansion of the layer to effect contact and capture of a targeted portion of the specimen. In the case of Bonner et al. (US 6,420,132), the activatable layer expands by melting of the layer to effect contact and capture which in effect causes vapor bubble formation, just as recited in the instant claimed invention.

5. Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Baer et al. (US 5,985,085).

Baer et al. disclose a process of laser capture microdissection from a specimen by providing a selectively activatable layer (transfer film) coupled to a substrate surface which includes a protrusion that provides controllable spacing between the selectively activatable layer and the specimen (see column 3, lines 43-49). The selectively

Art Unit: 1641

activatable layer integrates a substantially planarized EVA polymer that is hot vacuum baked which expands both up and down when it is exposed to laser energy (see column 7, lines 46-67). In practice, upon exposure to laser energy, the selectively activatable layer expands against the substrate surface then contacts a targeted portion on the specimen; thereby injecting itself into the specimen. Where there is a space between the activatable layer and the specimen surface, volumetric expansion is projected through the space then is caused to contact the targeted portion on the surface of the specimen.

***Response to Arguments***

6. Applicant's arguments filed 5/3/02 have been fully considered but they are not persuasive.

Applicant argues that Goldstein et al. does not teach the claimed invention because in Goldstein et al., a surface having a convex geometry is contacted with the specimen and only after contact, does the laser activation occur. Applicant argues that in the claimed invention, there is always maintained a spatial interval between the specimen on one hand and the activatable layer on the other hand so that when activation occurs, the activated portion "expands out", bridging the gap or interval between the specimen and the layer.

Contrary to Applicant's contention, Goldstein et al., indeed, inherently anticipate the claimed invention. Specifically, Goldstein et al. provide a convex surface maintained at a finite distance made up of selectively activatable layer which is

activated by heat and which includes strong long chain thermoplastic polymers that can undergo heat generated volumetric expansion such as ethylene vinyl acetate (EVA) and which has an intrinsic absorption capability at 3 to about 10 micrometers (see columns 8-9, 11, and 13). Further in claim 3 of the reference, Goldstein et al. teach directly extracting targeted material from a specimen by selectively activating the activatable layer first to cause a volumetric expansion, then contacting the activatable layer with the targeted portion. Therefore, claims 1-15 are said to be anticipated by Goldstein et al.

Specifically, Applicant's amendment and arguments fail to clearly point out the patentable novelty of the claimed invention in view of the state of the art disclosed by the references cited or the objections made.

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday, 6:30 AM - 4:00 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 308-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Art Unit: 1641

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gailene R. Gabel  
Patent Examiner  
Art Unit 1641  
August 21, 2002

CHRISTOPHER L. CHIN  
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GROUP 1800/1641